PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel Altman
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	05 JUN 2006
Applicant's or agent's file reference ANVIL.001BPC	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/36987	13 October 2005	13 October 2004

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F00206 (2006.01)
USPC - 623/1.35, 1.15, 1.16

Applicant ANVIL MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	10 March 2006	Lee W. Young Telephone No. 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/36987

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/36987

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-11, 14-28, drawn to a prosthesis and deployment catheter system having at least one frond.

Group II, claims 12-13, drawn to a prosthesis and deployment system assembly, comprising: an elongate, flexible catheter body; a balloon on the body, the balloon having an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in between the first and second sections; and a prosthesis carried by the balloon; wherein the prosthesis has a wall having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition.

Group III, claim 29, drawn to a dual guidewire catheter for treating vascular bifurcation.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of a prosthesis and deployment catheter system having at least one frond as in Group I is not present in Groups II and/or III; the special technical feature of a prosthesis and deployment system assembly, comprising: an elongate, flexible catheter body; a balloon on the body, the balloon having an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in between the first and second sections; and a prosthesis carried by the balloon; wherein the prosthesis has a wall having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition of Group II is not present in Group I and/or Group III; the special technical feature of the specifics of a dual guidewire catheter for treating vascular bifurcation as in Group III is not present in Groups I and/or II.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-11, 14-28

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/36987

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-11, 14-28	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-11, 14-28	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-11, 14-28	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-11 and 14-28 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the limitations of claims 1 and 14 including a prosthesis for placement at an opening from a main body lumen to a branch body lumen, the prosthesis having both one or a plurality of fronds extending axially from an end of the support and configured to be positioned across the Os and into the main body lumen and at least one circumferential link connected to the frond(s), the circumferential link spaced axially apart from the support, wherein the circumferential link is carried by a second portion of a balloon which is inflatable to a second diameter that is larger than the first diameter. Close prior art is US 5868777 to Lam. Lam discloses that after the ostial stent is positioned within the diseased bifurcated vessel, balloon catheters are employed to secure the ostial stent in position. By expanding the balloon carrying the ostial stent, the tubular body is seated within the diseased portion of the bifurcated vessel extending away from the bifurcation and the flaring portion is configured to "cap" the ostium to the diseased portion of the vessel. In the alternative, a series of various sized and shaped balloon catheters can be employed to configure the ostial stent so that it seats within and "caps" the ostium to the diseased portion of the bifurcation or a bi- or tri-balloon system may be employed to properly implant the tubular body and flaring portion of the ostial stent (col 3 ln 42-54). Furthermore, Lam discloses a flaring portion 25 is capable of expanding and may be comprised of individual pedals 26 or in the alternative and as shown in FIGS. 4 and 5, the flaring portion 25 may comprise malleable material 28 (col 5 ln 65 - col 6 ln 1). It is clear from Lam's figures 4 and 5 that the flaring portion 25 (which might be construed as a circumferential link is connected to and not spaced axially apart from the support.)

Claims 1-11 and 14-28 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.